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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/690,203

10/20/2003

Kenneth E. Kadziauskas

3109

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33357 7590 07/08/2010
ABBOTT MEDICAL OPTICS, INC.
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EXAMINER

MENDEZ, MANUEL A

ART UNIT

PAPER NUMBER

3763

MAIL DATE

DELIVERY MODE

07/08/2010

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/690,203	Applicant(s) KADZIAUSKAS ET AL.	
	Examiner Manuel A. Mendez	Art Unit 3763	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 08 March 2010.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 19-27, 32 and 33 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 19-27, 32, and 33 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 23 October 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>03/24/2010</u> . | 6) <input type="checkbox"/> Other: _____ |

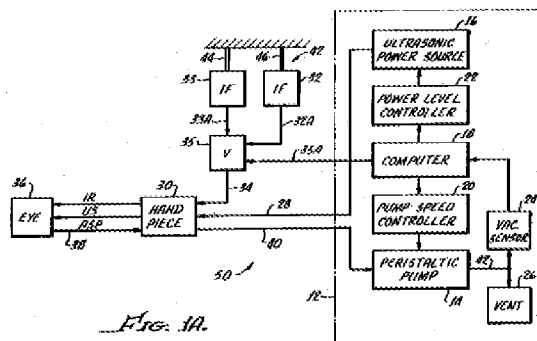
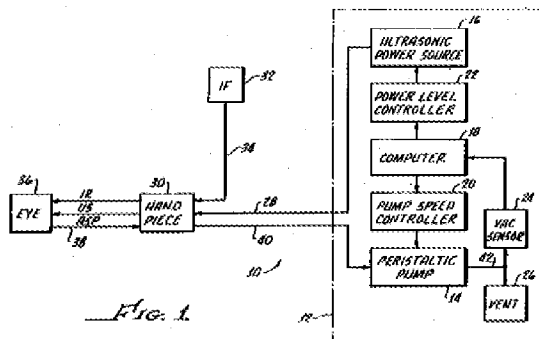
DETAILED ACTION

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 19-20, 23-27, and 32-33 are rejected under 35 U.S.C. 103(a) as being unpatentable over **Barwick, Jr. et al.** (US 5700240; hereafter Barwick) in view of **Murry et al.** (US 4156187; hereafter Murry) or **WO 9207622**.



The Barwick patent discloses a handpiece (30), a control console (column 1, line 67), irrigation and aspiration sources for removing fluid, and a matrix comprising power levels and fluid flow conditions.

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15 A sensor is connected in fluid communication with the handpiece for sensing vacuum levels in the hand-piece, and a control unit responsive to the sensed vacuum levels in the handpiece is provided for selecting one of the plurality of pressures of irrigation fluid introduced to the handpiece.

20 More particularly, a phacoemulsification hand-piece may be included, and a power source connected thereto is provided for supplying ultrasonic power to the handpiece. In this instance, the control unit is responsive to the sensed vacuum level in the handpiece for varying at least one of the speed of the pump, the ultrasonic power level provided to the handpiece and the pulse duty cycle of the ultrasonic
25 power provided to the handpiece by the power source.

The Barwick patent does not explicitly disclose that the matrix or algorithm in Barwick will create conditions that will not generate sufficient heat to create damage to tissue. However, it is self-evident from the teachings in the specification that the matrix is designed to prevent excessive heat that would damage tissue. In column 5, starting in line 61, the specification indicates that the matrix is constantly monitoring vacuum levels to determine if an occlusion condition is present. Any artisan skilled in the art would have recognized that if an occlusion occurs, fluid flow in the system is drastically reduced resulting in an increase in temperature levels that could damage tissue. Conclusively, the matrix in the Barwick patent inherently maintains conditions to prevent damage to tissue due to excessively high temperature levels.

In order to further clarify the issue of "damage to tissue", both Murry and WO 9207622 explicitly disclose the monitoring of multiple conditions to control power levels to a handpiece in order to prevent damage to tissue.

The specification in the Murray patent states:

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"WHEN ULTRASOUND IS ADDITIONALLY USED THERE HAS BEEN CONCERN ABOUT THE EXPOSURE OF THE TISSUE TO THE RADIATION AND OCCASIONALLY TO ITS HEATING EFFECT, YET FEW IF ANY INSTRUMENTS IN USE TODAY HAVE BEEN ABLE TO MEASURE THE TRUE POWER IN WATTS PER UNIT OF TIME, OR IN OTHER WORDS, THE TIME RATE OF DOING WORK APPLIED TO THE TISSUE. The reason for this is not because this data is not necessary and required but due to the fact that the instrumentation has not been available heretofore to obtain or control this unique form of energy.

Another discovery was that the same equipment used for irrigation, aspiration and applying measured ultrasonic power to biological tissues frequently must also apply medication such as drugs or treatment fluids, for example, to the cavity or tissue being invaded in a manner similar to the heart-lung machine wherein the medicines are supplied to the machine rather than directly to the patient.

Our study has illustrated that a total consideration of the problem requires analysis of at least the following areas:

- A. Irrigation
- B. Aspiration
- C. Medication
- D. Power Control
- E. Duration Control
- F. Supplementary Devices".

Based on the on the above observations and evidence provided, for a person of ordinary skill in the art, modifying the Barwick patent with a matrix designed to change power levels in a handpiece to prevent tissue damage based on changes to Factors A through F above, as taught by Murry, would have been considered obvious in view of the conventionality of such matrix or algorithm, and moreover, because such matrix

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would have provided improved monitoring of multiple factors to prevent tissue damage due to the heating effect.

WO 9207622 discloses an energy radiation applicator designed to elevate the temperature of tissue and a matrix designed to maintain the temperature level within specified parameters in order to avoid tissue damage. WO 9207622 demonstrates the importance of preventing tissue damage by sensing temperature levels in a radiated area and maintaining the temperature in the area within specified range. Accordingly, for a person of ordinary skill in the art, modifying the matrix or algorithm disclosed by Barwick, with a matrix or algorithm specifically designed to prevent damage to tissue, as taught by WO 9207622, would have been considered obvious in view of the conventionality of such matrix or algorithm, and moreover, because such matrix would have provided improved monitoring of multiple factors to prevent tissue damage due to the heating effect.

In relation to claims 20, 24-27, and 32-33, in column 4, line 22, the specification of Barwick discloses a control unit that is responsive to:

- vacuum levels in the handpiece, which is a fluid flow condition, for changing the speed of the irrigation pump and for changing the pressure of irrigation, and
- the ultrasonic power levels in the handpiece, and
- the pulsed duty cycle supplied by the power source.

In relation to claim 23, column 5, line 27, discloses a microprocessor computer (18).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 21 and 22 are rejected under 35 U.S.C. 103(a) as being unpatentable over **Barwick, Jr. et al.** (US 5700240; hereafter Barwick) in view of **Murry et al.** (US 4156187; hereafter Murry) or **WO 9207622**, as applied to Claims 19-20, 23-27, and 32-33, and in further view **Costin** (US 5733256) or **Lo et al.** (US 4954960; hereafter Lo).

Barwick does not disclose a flow sensor or a temperature sensor. However, these enhancements would have been considered conventional in the art as evidenced by the teachings of Costin and Lo.

The Costin patent discloses the use flow sensors (104/106) and the Lo patent demonstrates the conventionality of using temperature sensors to monitor the temperature of a probe or handpiece.

Based on the above observations, for a person of ordinary skill in the art, modifying the apparatus disclosed by Barwick with a flow sensor, as taught by Costin, and a temperature sensor, as taught by Lo, would have been considered obvious in view of the proven conventionality of these enhancements, and moreover, because both of these sensors would have enhanced the capabilities of the system by providing a more accurate control of the handpiece during surgical procedures.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Manuel A. Mendez whose telephone number is 571-272-4962. The examiner can normally be reached on 0730-1800 hrs.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mr. Nicholas D. Lucchesi can be reached on 571-272-4977. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Manuel A. Mendez/

Primary Examiner, Art Unit 3763

Manuel A. Mendez
Primary Examiner
Art Unit 3763

MM

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